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DOCKET NO: B0801.70280US01

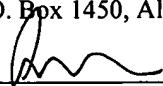
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Tzianabos et al.  
Serial No: 10/814,620  
Confirmation No: Not Yet Assigned  
Filed: March 31, 2004  
For: ZWITTERIONIC IMMUNOMODULATORS FOR THE  
TREATMENT OF ASTHMA AND ALLERGY

Examiner: Not Yet Assigned  
Art Unit: Not Yet Assigned

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 18th day of June, 2004.

  
Alan W. Steele, M.D., Ph.D., Reg. No. 45,128

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:


Transmitted herewith are the following documents:

- ☒ Statement Filed Pursuant to the Duty of Disclosure Under 37 CFR §§ 1.56, 1.97 and 1.98
- ☒ PTO Form 1449 with cited references
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
Tzianabos et al., *Applicant*

By:   
Alan W. Steele, M.D., Ph.D., Reg. No. 45,128  
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Docket No. B0801.70280US01  
Date: June 18, 2004  
X06/31/04X



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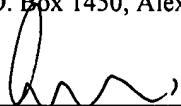
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Alan W. Steele, M.D., Ph.D., Reg. No. 45,128

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. § 1.97**

This Information Disclosure Statement has been filed within three months of the filing date of a National Application other than a continued prosecution application under 37 C.F.R. § 1.53(d) and before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application. The Applicant would like to bring to the Examiner's attention the following co-pending applications (copies enclosed\*) that may contain subject matter related to this application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Docket No.</u>	<u>Inventor(s)</u>
09/540,024	03/31/2000	B0801.70169US00	Tzianabos et al.
10/388,390	03/13/2003	B0801.70279US00	Comstock et al.
10/432,406	12/05/2001	B0801.70199US01	Wang et al.
10/848,779	05/19/2004	B0801.70169US01	Tzianabos et al.

\*except for 10/432,406 and 10/388,390, which are published applications listed in the accompanying Form 1449

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.


By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. § 102.

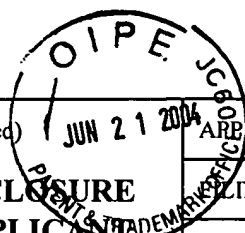
Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
Tzianabos et al., *Applicant*

By:   
Alan W. Steele, M.D., Ph.D., Reg. No. 45,128  
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Telephone: (617) 646-8000

Docket No. B0801.70280US01  
Date: June 18, 2004  
**X06/31/04X**



FORM PTO-1449/A and B (Modified)		APPLICATION NO.: 10/814,620	ATTY. DOCKET NO.: B0801.70280US01
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		FILED DATE: March 31, 2004	CONFIRMATION NO.: Not Yet Assigned
		APPLICANT: Tzianabos et al.	
Sheet 1 of 3		GROUP ART UNIT: Not Yet Assigned	EXAMINER: Not Yet Assigned

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	5,679,654		Tzianabos et al.	10-21-1997
	A2	5,700,787		Tzianabos et al.	12-23-1997
	A3	2002/0090357	A1	Barrat et al.	07-11-2002
	A4	2003/0219413	A1	Comstock et al.	11-27-2003
	A5	2004/0092433	A1	Wang et al.	05-13-2004

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B1	WO	00/59515	A2	The Brigham and Women's Hospital, Inc.	10-12-2000	
	B2	WO	02/45708	A2	The Brigham and Women's Hospital, Inc.	06-13-2002	
	B3	WO	03/075953	A2	Eli Lilly and Company	09-18-2003	

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	C1	AKBARI O et al., Antigen-specific regulatory T cells develop via the ICOS-ICOS-ligand pathway and inhibit allergen-induced airway hyperreactivity. Nat Med. 2002 Sep;8(9):1024-32. Epub 2002 Jul 29.		
	C2	BARRAT FJ et al., In vitro generation of interleukin 10-producing regulatory CD4(+) T cells is induced by immunosuppressive drugs and inhibited by T helper type 1 (Th1)- and Th2-inducing cytokines. J Exp Med. 2002 Mar 4;195(5):603-16.		
	C3	BAUMANN H et al., Structural elucidation of two capsular polysaccharides from one strain of Bacteroides fragilis using high-resolution NMR spectroscopy. Biochemistry. 1992 Apr 28;31(16):4081-9.		
	C4	BRUBAKER JO et al., Mitogenic activity of purified capsular polysaccharide A from Bacteroides fragilis: differential stimulatory effect on mouse and rat lymphocytes in vitro. J Immunol. 1999 Feb 15;162(4):2235-42.		
	C5	DIFABIO JL et al., Structure of the capsular polysaccharide antigen of type IV group B Streptococcus. Can. J. Chem. 1989; 67: 877-882.		
	C6	FINBERG RW et al., Decay-accelerating factor expression on either effector or target cells inhibits cytotoxicity by human natural killer cells. J Immunol. 1992 Sep 15;149(6):2055-60.		
	C7	FOURNIER JM et al., Isolation of type 5 capsular polysaccharide from Staphylococcus aureus. Ann Inst Pasteur Microbiol. 1987 Sep-Oct;138(5):561-7.		
	C8	GENBANK Accession Number AJ277832; Hutloff; 19-Jan-2001.		
	C9	GENBANK Accession Number CAC06612; Hutloff; 19-Jan-2001.		
	C10	GENBANK Accession Number NM_012092; 20-Dec-2003.		

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				GROUP ART UNIT: Not Yet Assigned	EXAMINER: Not Yet Assigned
Sheet	2	of	3		

C11	GENBANK Accession Number NP_036224; 20-Dec-2003.		
C12	GLAZEBROOK J et al., A novel exopolysaccharide can function in place of the calcofluor-binding exopolysaccharide in nodulation of alfalfa by <i>Rhizobium meliloti</i> . <i>Cell</i> . 1989 Feb 24;56(4):661-72.		
C13	GROUX H et al., A CD4+ T-cell subset inhibits antigen-specific T-cell responses and prevents colitis. <i>Nature</i> . 1997 Oct 16;389(6652):737-42.		
C14	GROUX H, Type 1 T-regulatory cells: their role in the control of immune responses. <i>Transplantation</i> . 2003 May 15;75(9 Suppl):8S-12S.		
C15	HAMELMANN E et al., Noninvasive measurement of airway responsiveness in allergic mice using barometric plethysmography. <i>Am J Respir Crit Care Med</i> . 1997 Sep;156(3 Pt 1):766-75.		
C16	HAREGEWOIN A et al., Human gamma delta+ T cells respond to mycobacterial heat-shock protein. <i>Nature</i> . 1989 Jul 27;340(6231):309-12.		
C17	HUTLOFF A et al., ICOS is an inducible T-cell co-stimulator structurally and functionally related to CD28. <i>Nature</i> . 1999 Jan 21;397(6716):263-6.		
C18	JENNINGS HJ et al., Structure of the complex polysaccharide C-substance from <i>Streptococcus pneumoniae</i> type 1. <i>Biochemistry</i> . 1980 Sep 30;19(20):4712-9.		
C19	JONULEIT H et al., Identification and functional characterization of human CD4(+)CD25(+) T cells with regulatory properties isolated from peripheral blood. <i>J Exp Med</i> . 2001 Jun 4;193(11):1285-94.		
C20	JONULEIT H et al., The regulatory T cell family: distinct subsets and their interrelations. <i>J Immunol</i> . 2003 Dec 15;171(12):6323-7.		
C21	KALKA-MOLL WM et al., Effect of molecular size on the ability of zwitterionic polysaccharides to stimulate cellular immunity. <i>J Immunol</i> . 2000 Jan 15;164(2):719-24.		
C22	KALKA-MOLL WM et al., Immunochemical and biological characterization of three capsular polysaccharides from a single <i>Bacteroides fragilis</i> strain. <i>Infect Immun</i> . 2001 Apr;69(4):2339-44.		
C23	KENNE L et al., Structural studies of the O-specific side-chains of the <i>shigella sonnei</i> phase I lipopolysaccharide. <i>Carbohydr. Res</i> . 1980 Jan 1;78(1):119-26.		
C24	KENNEDY R et al., Prevention of experimental postoperative peritoneal adhesions by N,O-carboxymethyl chitosan. <i>Surgery</i> . 1996 Nov;120(5):866-70.		
C25	KNIREL YA et al., Somatic antigens of <i>Pseudomonas aeruginosa</i> . The structure of O-specific polysaccharide chains of lipopolysaccharides of <i>P. aeruginosa</i> O3 (Lanyi), O25 (Wokatsch) and Fisher immunotypes 3 and 7. <i>Eur J Biochem</i> . 1987 Sep 15;167(3):549-61.		
C26	LINDBERG B et al., Structural studies of the capsular polysaccharide from <i>streptococcus pneumoniae</i> type 1. <i>Carbohydr. Res</i> . 1980 Jan 1;78(1):111-7.		
C27	MÄKELÄ MJ et al., IL-10 is necessary for the expression of airway hyperresponsiveness but not pulmonary inflammation after allergic sensitization. <i>Proc Natl Acad Sci U S A</i> . 2000 May 23;97(11):6007-12.		
C28	MOJTABAVI N et al., Long-lived Th2 memory in experimental allergic asthma. <i>J Immunol</i> . 2002 Nov 1;169(9):4788-96.		
C29	OH JW et al., CD4 T-helper cells engineered to produce IL-10 prevent allergen-induced airway hyperreactivity and inflammation. <i>J Allergy Clin Immunol</i> . 2002 Sep;110(3):460-8.		
C30	ONDERDONK AB et al., Evidence for T cell-dependent immunity to <i>Bacteroides fragilis</i> in an intraabdominal abscess model. <i>J Clin Invest</i> . 1982 Jan;69(1):9-16.		
C31	PANTOSTI A et al., Immunochemical characterization of two surface polysaccharides of <i>Bacteroides fragilis</i> . <i>Infect Immun</i> . 1991 Jun;59(6):2075-82.		
C32	RONCAROLO MG et al., Type 1 T regulatory cells. <i>Immunol Rev</i> . 2001 Aug;182:68-79.		
C33	SHARPE AH et al., The B7-CD28 superfamily. <i>Nat Rev Immunol</i> . 2002 Feb;2(2):116-26.		
C34	SHEVACH EM, CD4+ CD25+ suppressor T cells: more questions than answers. <i>Nat Rev Immunol</i> . 2002 Jun;2(6):389-400.		
C35	SURI-PAYER E et al., CD4+CD25+ T cells inhibit both the induction and effector function of autoreactive T cells and represent a unique lineage of immunoregulatory cells. <i>J Immunol</i> . 1998 Feb 1;160(3):1212-8.		

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Sheet	3	of	3				

	C36	SZU SC et al., Relation between structure and immunologic properties of the Vi capsular polysaccharide. Infect Immun. 1991 Dec;59(12):4555-61.		
	C37	TAYLOR RL et al., Stoichiometric depolymerization of polyuronides and glycosaminoglycuronans to monosaccharides following reduction of their carbodiimide-activated carboxyl groups. Biochemistry. 1972 Apr 11;11(8):1383-8.		
	C38	TOURNOY KG et al., Endogenous interleukin-10 suppresses allergen-induced airway inflammation and nonspecific airway responsiveness. Clin Exp Allergy. 2000 Jun;30(6):775-83.		
	C39	TZIANABOS AO et al., Polysaccharide-mediated protection against abscess formation in experimental intra-abdominal sepsis. J Clin Invest. 1995 Dec;96(6):2727-31.		
	C40	TZIANABOS AO et al., Structural characteristics of polysaccharides that induce protection against intra-abdominal abscess formation. Infect Immun. 1994 Nov;62(11):4881-6.		
	C41	TZIANABOS AO et al., Structural features of polysaccharides that induce intra-abdominal abscesses. Science. 1993 Oct 15;262(5132):416-9.		
	C42	TZIANABOS AO et al., Structural rationale for the modulation of abscess formation by Staphylococcus aureus capsular polysaccharides. Proc Natl Acad Sci U S A. 2001 Jul 31;98(16):9365-70. Epub 2001 Jul 24.		
	C43	TZIANABOS AO et al., T cells activated by zwitterionic molecules prevent abscesses induced by pathogenic bacteria. J Biol Chem. 2000 Mar 10;275(10):6733-40.		
	C44	TZIANABOS AO et al., The capsular polysaccharide of Bacteroides fragilis comprises two ionically linked polysaccharides. J Biol Chem. 1992 Sep 5;267(25):18230-5.		
	C45	VAN SCOTT MR et al., IL-10 reduces Th2 cytokine production and eosinophilia but augments airway reactivity in allergic mice. Am J Physiol Lung Cell Mol Physiol. 2000 Apr;278(4):L667-74.		
	C46	VANN WF et al., The structure of the capsular polysaccharide (K5 antigen) of urinary-tract-infective Escherichia coli 010:K5:H4. A polymer similar to desulfo-heparin. Eur J Biochem. 1981 May 15;116(2):359-64.		
	C47	WANG Y et al., Structural basis of the abscess-modulating polysaccharide A2 from Bacteroides fragilis. Proc Natl Acad Sci U S A. 2000 Dec 5;97(25):13478-83.		
	C48	WESSELS MR et al., Structure and immunochemistry of an oligosaccharide repeating unit of the capsular polysaccharide of type III group B Streptococcus. A revised structure for the type III group B streptococcal polysaccharide antigen. J Biol Chem. 1987 Jun 15;262(17):8262-7.		

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - Must provide a copy of any patent, publication, other information listed, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]